

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

Hasegawa et al.

Application No. 10/567,766

Filed: February 10, 2006

Confirmation No. 5560

Group Art Unit: Unassigned

Examiner: Unassigned

For: NOVEL VACCINE CONTAINING  
ADJUVANT CAPABLE OF INDUCING  
MUCOSAL IMMUNITY

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.97 and 1.98, the references listed on the enclosed Form PTO-1449 and/or Substitute Form PTO-1449 ("Form 1449") are submitted for consideration by the Examiner in the examination of the above-identified patent application.

The full consideration of the references in their entirety by the Examiner is respectfully requested and encouraged. Also, it is respectfully requested that the references be entered into the record of the present application and that the Examiner place his or her initials in the appropriate area on the enclosed Form 1449, thereby indicating the Examiner's consideration of each of the references.

The submission of the references listed on the Form 1449 is for the purpose of providing a complete record and is not a concession that the references listed thereon are prior art to the invention claimed in the patent application. The right is expressly reserved to establish an invention date earlier than the above-identified filing date in order to remove any reference submitted herewith as prior art should it be deemed appropriate to do so.

Further, the submission of the references is not to be taken as a concession that any reference represents art that is relevant or analogous to the claimed invention. Accordingly, the right to argue that any reference is not properly within the scope of prior art relevant to an examination of the claims in the above-identified application is also expressly reserved.

The Information Disclosure Statement is being filed:

- ☒ **within** any one of the following time periods: (a) within three months of the filing date of a national application other than a continued prosecution application under 37 CFR 1.53(d); (b) within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 of an international application; (c) before the mailing date of a

first Office Action on the merits; or (d) before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

- ☐ **after** (a), (b), (c) or (d) above, but before the mailing date of a final action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and includes *one* of:

☐ the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below).

*or*

☐ the fee of \$180 set forth in 37 CFR 1.17(p) (see "Fees" below).

- ☐ **after** the mailing date of a final action under 37 CFR 1.113 or a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and on or before payment of the issue fee, and includes the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).

- ☐ **after** the mailing date of a Notice of Allowance under 37 CFR 1.311, and on or before payment of the issue fee, and **within** thirty days of receiving each item of information contained in the Information Disclosure Statement, and includes the Statement under 37 CFR 1.704(d) (see "Statement under 37 CFR 1.704(d)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).

NOTE: This is for original applications except applications for a design patent, filed on or after May 29, 2000, wherein a paper containing only an Information Disclosure Statement in compliance with 37 CFR 1.97 and 1.98 is being filed.

### Copies of the References

- ☐ Copies of all of the references listed on the enclosed Form 1449 are enclosed herewith.

- ☒ Attached to each reference not in the English language is a concise explanation of the relevance pursuant to 37 CFR 1.98(a)(3). An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of the relevance pursuant to 37 CFR 1.98(a)(3).

- ☒ A copy of the international search report is enclosed herewith.

- ☐ The references listed on the enclosed Form 1449 were previously identified in the parent application(s) of the present application, and copies of the references were furnished at that time. Accordingly, additional copies of the references are not submitted herewith, so as not to burden the file with duplicate copies of references. The Examiner is respectfully requested to carefully review the references in accordance with the requirements set out in the Manual of Patent Examining Procedure. In accordance with 37 CFR 1.98(d), the details of the parent application(s) relied upon for an earlier filing date under 35 USC 120 in which copies of the references were previously furnished are set out below:

U.S. APPLICATIONS		Status ( <i>check one</i> )		
U.S. APPLICATIONS	U.S. FILING DATE	PATENTED	PENDING	ABANDONED
1.				
2.				
3.				

**Statement under 37 CFR 1.97(e)**

- ☐ The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.
- ☐ The **undersigned** hereby states that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

**Statement under 37 CFR 1.704(d)**

- ☐ The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

**Fees**

- ☒ No fee is owed by the applicant(s).  
☐ The **IDS Fee of \$180** under 37 CFR 1.17(p) is enclosed herewith.

**Method of Payment of Fees**

- ☐ Charge Deposit Account No. 12-0913 in the amount of \$ .

**Authorization to Charge Additional Fees**

- ☒ If any additional fees are owed in connection with this communication, please charge Deposit Account No. 12-0913.

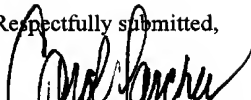
In re Application of Hasegawa et al.  
Application No. 10/567,766

**Instructions as to Overpayment**

☒  
☐

Credit Account No. 12-0913.  
Refund

Respectfully submitted,



Carol Larcher, Reg. No. 35,243  
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(312) 759-5646 (facsimile)

Date: December 29, 2006

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**CERTIFICATION UNDER 37 CFR 1.8**

I hereby certify that this INFORMATION DISCLOSURE STATEMENT (along with any documents referred to as being attached or enclosed) is being electronically filed via EFS WEB addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Date: December 29, 2006

  
Mark J. Sweetin

Substitute for FORM 1449A/B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 2

**Complete if Known**

Application Number:	10/567,766
Filing Date:	February 10, 2006
First Named Inventor:	Hideki Hasegawa
Group Art Unit:	Unassigned
Confirmation Number:	5560
Examiner Name:	Unassigned
Attorney Docket Number:	43512-103808

**U.S. PATENT DOCUMENTS**

Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
		Application or Patent Number	Kind Code			
	AA	3,906,092		Hilleman et al.	Sep. 16, 1975	
	AB	4,024,222		Ts'o et al.	May 17, 1977	
	AC	4,130,641		Ts'o et al.	Dec. 19, 1978	
	AD	4,795,744		Carter	Jan. 3, 1989	
	AE	4,820,696		Carter	Apr. 11, 1989	
	AF	4,945,082		Carter	July 31, 1990	
	AG	4,950,652		Carter	Aug. 21, 1990	
	AH	4,963,532		Carter	Oct. 16, 1990	
	AI	5,063,209		Carter	Nov. 5, 1991	
	AJ	5,091,374		Carter	Feb. 25, 1992	
	AK	5,194,245		Carter	Mar. 16, 1993	
	AL	5,712,257		Carter	Jan. 27, 1998	
	AM	5,906,980		Carter	May 25, 1999	
	AN	6,130,206		Carter	Oct. 10, 2000	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Doc. No.	Foreign Patent Document			Name of Patentee or Applicant	Date of Publication	Translation	
		Office	Application or Patent Number	Kind Code			Yes	No**
	AO	JP	50-082226		The Johns Hopkins University	Jul. 3, 1975		X*
	AP	JP	62-077334		Hem Res. Inc.	Apr. 9, 1987		X*
	AQ	JP	64-90126		Hem Res. Inc.	Apr. 6, 1989		X*
	AR	JP	2005516294	T	Loeb Health Research Institute at the Ottawa Hospital	Jun. 4, 2002		X*
	AS	JP	2002526425	T	The Regents of the University of California	Aug. 20, 2002		X*
	AT	JP	2002536293	T	Children's Hospital Medical Center	Oct. 29, 2002		X*
	AU	JP	2003510282	T	University of Iowa Research Foundation	Mar. 18, 2003		X*
	AV	WO	99/61056	A2	Loeb Health Research Institute at the Ottawa Hospital et al.	Dec. 2, 1999		
	AW	WO	00/20039	A1	The Regents of the University of California	Apr. 13, 2000		
	AX	WO	00/26380	A1	Children's Hospital Medical Center	May 11, 2000		
	AY	WO	01/22972	A2	Iowa State University Research Foundation et al.	Apr. 5, 2001		

EXAMINER

DATE CONSIDERED

\* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

+ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).

<b>Substitute for FORM 1449A/B/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i> <b>Sheet 2 of 2</b>	<b>Complete if Known</b>	
	Application Number:	10/567,766
	Filing Date:	February 10, 2006
	First Named Inventor:	Hideki Hasegawa
	Group Art Unit:	Unassigned
	Confirmation Number:	5560
	Examiner Name:	Unassigned
	Attorney Docket Number:	43512-103808

OTHER - NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Doc. No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Translation	
			Yes	No**
	A Z	Avramidis et al., "Adjuvant Regulation of Cytokine Profile and Antibody Isotype of Immune Responses to Mycoplasma Agalactiae in Mice," <i>Veterinary Microbiology</i> , 88: 325-338 (2002).		
	B A	Knopf et al., "Antibody in Tears Following Intranasal Vaccination With Inactivated Virus: II. Enhancement of Tear Antibody Production By the Use of Polyinosinic: Polycytidilic Acid (Poly I:C)," <i>Investigative Ophthalmology</i> , 10:10 750-759 (1971)		
	B B	Knopf et al., "Antibody in Tears Following Intranasal Vaccination With Inactivated Virus: III. Role of Tear and Serum Antibody in Experimental Vaccinia Conjunctivitis," <i>Investigative Ophthalmology</i> , 10:10 760-769 (1971)		
	B C	Tamura et al., "Cross-Protection Against Influenza Virus Infection Afforded By Trivalent Inactivated Vaccines Inoculated Intranasally With Cholera Toxin B Subunit," <i>The Journal of Immunology</i> , 149:3 981-988 (1992).		
	B D	Turner et al., "Stimulation of Humoral and Cellular Antibody Formation In Mice By Poly I:C," <i>Proc. Soc. Exp. Biol. &amp; Med.</i> , 133: 334-338 (1970).		
	B E	Wang et al., "Noncoding RNA Danger Motifs Bridge Innate and Adaptive Immunity and Are Potent Adjuvants for Vaccination," <i>The Journal of Clinical Investigation</i> , 110:8 1175-1184 (2002).		

CHDS01 CLARCHER 372471v1

EXAMINER	DATE CONSIDERED
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\* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

+ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).